DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850


**MEDICARE PLAN ACCOUNTABILITY GROUP**

**DATE:** November 23, 2005

**TO:** All Prescription Drug Plan and Medicare Advantage Prescription Drug Plan Sponsors

**FROM:** Cynthia Moreno /s/
Acting Director

**SUBJECT:** Draft Medicare Part D Audit Guide – Instructions for review and comment

As discussed during the Part D call on November 16, 2005, CMS is herein providing a DRAFT document titled "Medicare Part D Audit Guide" for your review and comment. We appreciate that this is a very busy time for everyone involved in implementing the Part D benefit, so we are providing a three week window for you to review and comment on the guide. CMS will accept comments on this document until December 14, 2005. Please submit comments via email to **Part_D_Audit_Guide_Comments@cms.hhs.gov.**

The attached draft "Medicare Part D Audit Guide" includes the elements CMS will utilize while conducting regularly scheduled and focused audits of Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) sponsors. Audits are a necessary component of CMS' comprehensive oversight strategy to ensure and document compliance with the MMA statute, the Part D regulations, and contractual agreements. CMS' comprehensive oversight strategy for Part D Plan Sponsors is described in the document titled "Part D Oversight Strategy" found on the Prescription Drug Plans section of CMS' website [http://www.cms.hhs.gov/pdps/PlnRpt_Ovrsit.asp]. CMS will be developing additional guidance regarding the timing and scheduling of these audits. This guidance will be provided to you at a later date.

CMS' long-term goal for Medicare Advantage Organizations is to incorporate applicable Part D Audit Guide elements directly into the Medicare Advantage Monitoring Review Guide. We are also in the process of developing similar Part D Audit Guides for sponsors of other types of plans such as employer and cost plans.

Thank you for taking the time to review the draft "Medicare Part D Audit Guide," we look forward to receiving your insightful comments. CMS will carefully review all comments submitted, make necessary corrections, and have a final version of the guide available in January 2006.


# Medicare Part D Audit Guide
# Version 1.0

## November 23, 2005

## Table of Contents

| Code/ Type | Chapter 1: Enrollment and Disenrollment<br>For MA-PD sponsors, CMS granted a waiver of the requirements that Part D plan sponsors accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements, as these requirements are duplicative of Medicare Advantage (MA) requirements under 42 CFR § 422 Subpart B – Eligibility, Election, and Enrollment. MA-PD sponsors will conduct enrollment and determine eligibility consistent with MA program requirements, and are therefore subject to the MA Monitoring Review Guide for these requirements. | Review Result |
|---|---|---|
| | **Enrollment** | |
| **ER01 Sample Element** | **<u>Enrollment Forms</u>**<br><br>**The Part D plan sponsor must use an enrollment form and may use any enrollment mechanism that has been approved by CMS.**<br><br>**42 CFR § 423.32(b)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.1***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER02 Desk Element** | **<u>Incomplete Enrollment Requests</u>**<br><br>**If the enrollment request is incomplete, the Part D plan sponsor must document its efforts to obtain missing information or documentation needed to complete the enrollment request.**<br><br>**Attestation required by the PDP Solicitation: 3.5.A.7**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.2.2***<br>***Note: Refer to MA Guide for applicable MA-PD element*** | |
| **ER03 Desk Element** | **<u>Denial of Enrollment Requests</u>**<br><br>**If the Part D plan sponsor must deny an enrollment, it must occur no later than 7 business days from the date of receipt of the completed enrollment request. The Part D plan sponsor must provide a notice of denial to the individual that includes an explanation of the reason for the denial. This notice must be in a format and manner specified by CMS and must provided within 7 business days of the Part D plan sponsor's denial determination.**<br><br>**42 CFR § 423.32(c)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.2.3***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

| Code/ Type | Chapter 1: Enrollment and Disenrollment<br>For MA-PD sponsors, CMS granted a waiver of the requirements that Part D plan sponsors accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements, as these requirements are duplicative of Medicare Advantage (MA) requirements under 42 CFR § 422 Subpart B – Eligibility, Election, and Enrollment. MA-PD sponsors will conduct enrollment and determine eligibility consistent with MA program requirements, and are therefore subject to the MA Monitoring Review Guide for these requirements. | Review Result |
|---|---|---|
| **ER04 Sample Element** | **Notice Acknowledging the Receipt of Completed Enrollment Election**<br><br>**The Part D plan sponsor must send a notice acknowledging receipt of the completed enrollment request within 7 business days of its receipt, unless the Part D plan sponsor combines the acknowledgement and confirmation notice.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER05 Desk Element** | **Cancellations of Enrollment Requests**<br><br>**If a beneficiary verbally requests a cancellation of an enrollment request, the Part D plan sponsor must document the request and process the cancellation. The Part D plan sponsor must provide a notice to the individual that states that the cancellation is being processed within 7 business days of the receipt of the cancellation request. Note: Cancellation can only occur prior to effective date of enrollment.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 50.1***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER06 Sample Element** | **Enrollment Notice Requirement (Timeliness)**<br><br>**Once the Part D plan sponsor receives a reply listing report from CMS indicating whether the individual's enrollment has been accepted or rejected, the Part D plan sponsor must notify the individual of CMS' acceptance or rejection of the enrollment within 7 business days of the availability of the of the monthly TRR, or within 5 business days of receipt of the weekly "mini" TRR if the Part D plan sponsor provided all information and required notices together.**<br><br>**42 CFR § 423.32(d)**<br>**Attestation required by the PDP Solicitation: 3.5.A.7**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.4***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

| Code/ Type | Chapter 1: Enrollment and Disenrollment<br>For MA-PD sponsors, CMS granted a waiver of the requirements that Part D plan sponsors accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements, as these requirements are duplicative of Medicare Advantage (MA) requirements under 42 CFR § 422 Subpart B – Eligibility, Election, and Enrollment. MA-PD sponsors will conduct enrollment and determine eligibility consistent with MA program requirements, and are therefore subject to the MA Monitoring Review Guide for these requirements. | Review Result |
|---|---|---|
| **ER07 Sample Element** | **<u>Enrollment Notice Requirement (Notice Content)</u>**<br><br>**The Part D plan sponsor must provide the individual with a notice of CMS' acceptance or rejection of the enrollment in a format and manner specified by CMS.**<br><br>**42 CFR § 423.32(d)**<br>**Attestation required by the PDP Solicitation: 3.5.A.7**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER08 Desk Element** | **<u>Provision of Materials Prior to the Effective Date of Enrollment</u>**<br><br>**Prior to the effective date of enrollment, the Part D plan sponsor must provide the member with all the necessary information about being a Medicare member of the Part D plan, including the Part D plan rules and the member's rights and responsibilities. In cases where the Part D plan sponsor is unable to provide the materials prior to the effective date, it must provide the individuals all required materials no later than 7 business days after receipt of the complete enrollment request.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.4***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER09 Desk Element** | **<u>Auto-Enrollment of Full Benefit Dual-Eligible Beneficiaries</u>**<br><br>**The Part D plan sponsor must accept auto-enrollments in accordance with CMS procedures for full benefit dual eligible beneficiaries who have failed to enroll in a Part D plan.**<br><br>**42 CFR § 423.34(d)**<br>**Attestation required by the PDP Solicitation: 3.5.A.3**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.1.4***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

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| **ER10 Desk Element** | **<u>Facilitated Enrollment for Low Income Subsidy Eligible Individuals</u>**<br><br>**The Part D plan sponsor must accept facilitated enrollment in accordance with CMS procedures for low income subsidy eligible individuals.**<br><br>**Attestation required by the PDP Solicitation: 3.5.A.3**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 30.1.5***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER11 Desk Element** | **<u>Special Enrollment Period</u>**<br><br>**The Part D plan sponsor must develop policies and procedures for addressing beneficiary enrollment requests made during a Special Enrollment Period and verifying a beneficiary's eligibility for a Special Enrollment Period. The Part D plan sponsor recognizes the CMS Special Enrollment Period (SEP).**<br><br>**42 CFR § 423.38(c)**<br>**Attestations required by the PDP Solicitation: 3.4.5.A.2; 3.5.A.10**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 20.3***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **ER12 Desk Element** | **<u>Late Enrollment Penalty</u>**<br><br>**The Part D plan sponsor must collect a late enrollment penalty (LEP) from Part D eligible individuals who do not maintain creditable prescription drug coverage for a continuous period of sixty-three (63) days or longer following the end of the individual's initial enrollment period during which the individual met all of the following conditions: (i) The individual was eligible to enroll in a Part D plan; (ii) The individual was not covered under any creditable prescription drug coverage; and (iii) The individual was not enrolled in a Part D plan.**<br><br>**42 CFR § 423.46, 423.286(d)(3)**<br>***Creditable Coverage Guidance*** | |

| Code/ Type | Chapter 1: Enrollment and Disenrollment<br>For MA-PD sponsors, CMS granted a waiver of the requirements that Part D plan sponsors accept Part D plan enrollments and determine Part D plan eligibility consistent with Part D program requirements, as these requirements are duplicative of Medicare Advantage (MA) requirements under 42 CFR § 422 Subpart B – Eligibility, Election, and Enrollment. MA-PD sponsors will conduct enrollment and determine eligibility consistent with MA program requirements, and are therefore subject to the MA Monitoring Review Guide for these requirements. | Review Result |
|---|---|---|
| **ER13 Desk Element** | **<u>Enrollment Process – File and Retaining Requests</u>**<br><br>**The Part D plan sponsor must file and retain enrollment requests for the period specified in CMS instructions.**<br><br>**42 CFR § 423.36(b)(3); 423.505(e)(1)(iii)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| | **Disenrollment** | |
| **DN01 Sample Element** | **<u>Voluntary Disenrollment Process – Notice to Enrollee</u>**<br><br>**The Part D plan sponsor must provide the enrollee with a notice of disenrollment that CMS approves within 7 business days of receipt of disenrollment request from the individual, or within 7 business days of notification via the reply listing.**<br><br>**42 CFR § 423.36(b)(2)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.1.5***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN02 Desk Element** | **<u>Denial of Disenrollment Requests</u>**<br><br>**If the Part D plan sponsor receives a disenrollment request that it must deny, it must notify the enrollee within 7 business days of the receipt of the request, and must include the reason for the denial.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment*: Section 40.1.4**<br>**Attestation required by the PDP Solicitation: 3.5.A.8**<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN03 Desk Element** | **<u>Cancellations of Disenrollment Requests</u>**<br><br>**If a beneficiary verbally requests a cancellation of a disenrollment request, the Part D plan sponsor must document the request and process the cancellation. The Part D plan sponsor must provide a notice to the individual that states that the cancellation is being processed within 7 business days of the receipt of the cancellation request. Note: Cancellation can only occur prior to effective date of disenrollment.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 50.1***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

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|---|---|---|
| **DN04 Desk Element** | **<u>Voluntary Disenrollment Process – File and Retaining Requests</u>**<br><br>**The Part D plan sponsor must file and retain disenrollment requests for the period specified in CMS instructions.**<br><br>**42 CFR § 423.36(b)(3); 423.505(e)(1)(iii)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN05 Desk Element** | **<u>Inappropriate Involuntary Disenrollment or Encouragement to Disenroll</u>**<br><br>**The Part D plan sponsor must not involuntarily disenroll an individual, orally or in writing, or by any action or inaction, request or encourage an individual to disenroll. However, a Part D plan sponsor may disenroll an individual for (i) failure to pay premiums or (ii) disruptive behavior. The Part D plan sponsor *must* disenroll an individual for (i) loss of Part D eligibility, (ii) death of individual, (iii) a move outside the geographic area, (iv) misrepresentation of third-party reimbursement, or (v) plan termination.**<br><br>**42 CFR § 423.44(a)**<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN06 Sample Element** | **<u>Involuntary Disenrollment for Nonpayment of Premium (Optional)</u>**<br><br>**If the Part D plan sponsor disenrolls a member for failure to pay any monthly premium, it must send a notice of non-payment of premiums within 7 business days after the premium due date and must allow a minimum grace period of 1 month. The Part D plan sponsor must send a final disenrollment notice to the enrollee after the expiration of the grace period and before the disenrollment transaction is submitted to CMS. This notice must include an explanation of why the Part D plan sponsor is planning to disenroll the individual and an explanation of the individual's right to file a grievance under the Part D plan sponsor's grievance procedures. The Part D plan sponsor must also send a final confirmation of disenrollment after it has received confirmation from CMS.**<br><br>**42 CFR § 423.44(b)(1)(i); § 423.44(c); § 423.44(d)(1)**<br>**Attestation required by the PDP Solicitation: 3.5.A.12**<br>***Reporting Requirements for Section I: Enrollment and Eligibility: Section 40.3.1***<br>***PDP Guidance Eligibility, Enrollment and Disenrollment***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

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| **DN07 Desk Element** | **Involuntary Disenrollment for Disruptive Behavior (Optional)**<br><br>**The Part D plan sponsor may only disenroll a member for disruptive behavior after it has met CMS requirements for this action and received CMS' approval for the involuntary disenrollment.**<br><br>**42 CFR § 423.44(b)(1)(ii); § 423.44(c); § 423.44(d)(2)**<br>**Attestation required by the PDP Solicitation: 3.5.A.12**<br>***Reporting Requirements for Section I: Enrollment and Eligibility***<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.3.2***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN08 Desk Element** | **Involuntary Disenrollment for Fraud and Abuse (Optional)**<br><br>**If the Part D plan sponsor disenrolls a member for fraud and abuse, it must immediately notify the CMS Regional Office (RO) and give the individual notice of the disenrollment before the disenrollment transaction is submitted to CMS. The notice must include an explanation of why the Part D plan sponsor is planning to disenroll the individual and an explanation of the individual's right to file a grievance under the Part D plan sponsor's grievance procedures.**<br><br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.3.3***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

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|---|---|---|
| **DN09 Desk Element** | **Required Disenrollment for Move Out of Service Area**<br><br>**The Part D plan sponsor must disenroll an individual who notifies it that he or she no longer resides in the service area of a Part D plan; or if the Part D plan sponsor receives documented proof of a beneficiary address change that is outside the Part D plan service area from either CMS or from the U.S. Post Office. If the Part D plan sponsor learns of the move from CMS or the U.S. Post Office, it must make an attempt to contact the member to verify address information and document their efforts. If the Part D plan sponsor does not receive confirmation from the member (or his or her legal representative) within a six month period, it must initiate disenrollment. The six month period will begin on the date the change in address is identified (e.g. through the transaction reply report). The Part D plan sponsor must give the individual notice of the disenrollment within 7 business days of learning of the permanent move from the enrollee or no later than 7 business days after the 6 month period, and before the disenrollment transaction is submitted to CMS. The notice must include an explanation of why the Part D plan sponsor is planning to disenroll the individual and an explanation of the individual's right to file a grievance under the Part D plan sponsor's grievance procedures.**<br><br>**42 CFR § 423.44(b)(2)(i); § 423.44(c); § 423.44(d)(5)**<br>**Attestation required by the PDP Solicitation: 3.5.A.2**<br>***Reporting Requirements for Section I: Enrollment and Eligibility***<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.2.1***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN10 Desk Element** | **Required Disenrollment for Loss of Part D Eligibility**<br><br>**The Part D plan sponsor must disenroll an individual who loses eligibility for Part D and provide the individual notice of the disenrollment within 7 business days of reply listing.**<br><br>**42 CFR § 423.44(b)(2)(ii); § 423.44(c); § 423.44(d)(3)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.2.2***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |

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|---|---|---|
| **DN11 Desk Element** | **Required Disenrollment for Death of Individual**<br><br>**The Part D plan sponsor must disenroll an individual upon death of the individual and give the estate notice of the disenrollment within 7 business days of reply listing.**<br><br>**42 CFR § 423.44(b)(2)(iii); § 423.44(c)(2); § 423.44(d)(4)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.2.3***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN12 Desk Element** | **Required Disenrollment for Material Misrepresentation**<br><br>**The Part D plan sponsor must disenroll a member if the individual materially misrepresents information, as determined by CMS, to the Part D plan sponsor that the individual has or expects to receive reimbursement for third-party coverage, and provide the individual with notice of disenrollment in accordance with CMS requirements.**<br><br>**42 CFR § 423.44(b)(2)(v); § 423.44(c); § 423.44(d)(7)(i)**<br>***PDP Guidance Eligibility, Enrollment and Disenrollment: Section 40.2.5***<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **DN13 Desk Element** | **Enrollment and Disenrollment Reporting Requirements**<br><br>**The Part D plan sponsor must provide CMS with information concerning enrollment and disenrollment according to guidelines specified by CMS.**<br><br>***Reporting Requirements for Section I: Enrollment and Eligibility and Section V: Grievances*** | |

| Code/ Type | Chapter 2: Provider Communication | Review Result |
|---|---|---|
| **PC01 Desk Element** | **Toll-free Call Center**<br><br>**The Part D plan sponsor must operate a toll-free customer call center providing service for pharmacists and providers.**<br><br>**42 CFR § 423.128(d)(1)(i-ii)**<br>**Attestation required by the PDP Solicitation: 3.11.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.9.A.1** | |
| **PC02 Desk Element** | **Provision of Notice Regarding Formulary Changes**<br><br>**The Part D plan sponsor must provide at least 60 days notice to all authorized prescribers, network pharmacies, and pharmacists prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D plan sponsor must provide retrospective notice to all authorized prescribers, network pharmacies, and pharmacists.**<br><br>**42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |
| **PC03 Desk Element** | **Formulary Education**<br><br>**The Part D plan sponsor must establish and implement policies and procedures to educate and inform health care providers concerning the plan's formulary.**<br><br>**42 CFR § 423.120(b)(7)** | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| **MR01 Desk Element** | **Submission of Pricing and Pharmacy Network Information (www.medicare.gov)**<br><br>**The Part D plan sponsor must submit pricing and pharmacy network information for each Part D plan to CMS to be publicly reported on www.medicare.gov.**<br><br>**42 CFR § 423.48**<br>**Attestation required by the PDP Solicitation: 3.13.A.20**<br>**Attestation required by the MA-PD Solicitation: 3.11.A.17** | |
| **MR02 Desk Element** | **Submission and Distribution of Marketing Materials**<br><br>**For "non-model" documents and for "model" documents that the Part D plan sponsor modifies: The Part D plan sponsor must certify that Medicare marketing materials are in a format, and use acceptable terminology, and submit them for a 45 day review period by CMS. The Part D plan sponsor must not distribute or make such materials available until it receives notice from CMS that CMS has approved the materials, or until 45 days have expired and the Part D plan sponsor has not received notice from CMS that the materials have not been approved.**<br><br>**For "model" documents that the Part D plan sponsor uses without modification: The Part D plan sponsor must submit and certify that Medicare marketing materials are in a format, and use acceptable terminology, and submit them for a 10 day review period by CMS. The Part D plan sponsor must not distribute or make such materials available until it receives notice from CMS that CMS has approved the materials, or until 10 days have expired and the Part D plan sponsor has not received notice from CMS that the materials have not been approved.**<br><br>**42 CFR § 423.50(a)(1); § 423.50(a)(3)**<br>**Attestation required by the PDP Solicitation: 3.10.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.8.A.1**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***<br>***Reporting Requirements for Section V: Grievances*** | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| MR03 Desk Element | **File & Use Marketing Materials**<br><br>The Part D plan sponsor must certify that qualified materials for File & Use Certification comply with CMS requirements, and must wait 5 days to distribute these materials, unless a waiver has been granted. The Part D plan sponsor must submit at least 90% of materials that qualify for File & Use Certification under this process. If a Part D plan sponsor has File & Use Eligible status, it must submit qualified materials to CMS 5 days prior to use.<br><br>42 CFR § 423.50(a)(2-3)<br>Attestation required by the PDP Solicitation: 3.10.A.1<br>Attestation required by the MA-PD Solicitation: 3.8.A.1<br>*Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*<br>*Reporting Requirements for Section V: Grievances* | |
| MR04 Desk Element | **Requirements for Pre-enrollment Marketing Materials**<br><br>The Part D plan sponsor's pre-enrollment marketing materials must provide, in a format, print size, and using standard terminology specified by CMS, the information required by CMS to Medicare beneficiaries interested in enrolling.<br><br>42 CFR § 423.50(d)(1); § 423.50(d)(3); § 423.50(d)(4)<br>Attestation required by the PDP Solicitation: 3.10.A.1<br>Attestation required by the MA-PD Solicitation: 3.8.A.1<br>*Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*<br>*Information for Part D Sponsors on Requirements for a Transition Process* | |
| MR05 Desk Element | **Plan Offering and Public Notification of Enrollment Period**<br><br>The Part D plan sponsor must offer the same plan to all Part D eligible beneficiaries residing in that plan's service area, and must notify the general public of its enrollment period in an appropriate manner throughout its service area.<br><br>42 CFR § 423.50(d)(2); § 423.104(b) | |
| MR06 Desk Element | **No Engagement in Activities that Mislead, Confuse or Misrepresent**<br><br>The Part D plan sponsor must not engage in prohibited marketing activities that are materially inaccurate, materially mislead, confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D Plan.<br><br>42 CFR § 423.50(f)(1)<br>*Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans* | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| **MR07 Desk Element** | **Plan Responsibility for Persons Employed or Contracted to Perform Marketing**<br><br>**The Part D plan sponsor must have a compensation structure that meets CMS requirements for any person directly employed or contracted to market the plan. The Part D plan sponsor must utilize only state licensed, certified, or registered individuals to perform marketing on behalf of the Part D plan sponsor, whether as an employee or under contract directly or downstream, if a state has such a marketing requirement, and it must conduct monitoring activities to ensure that individuals marketing on behalf of the Part D plan sponsor comply with all applicable Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines, to ensure that beneficiaries receive truthful and accurate information.**<br><br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |
| **MR08 Desk Element** | **Marketing Materials Provided For Significant Non-English Speaking Populations**<br><br>**For markets with a significant non-English speaking population, the Part D plan sponsor provides marketing materials in the language of these individuals.**<br><br>**42 CFR § 423.50(d)(5)** | |
| **MR09 Desk Element** | **Marketing to the Disabled**<br><br>**The Part D plan sponsor must demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population.**<br><br>**42 CFR § 423.50(f)(2)(i)** | |
| **MR10 Desk Element** | **Provision of Notices Regarding Formulary Changes**<br><br>**Prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug, the Part D plan sponsor must provide a written notice to affected enrollees at least 60 days prior to the date the change becomes effective, or provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change at the time an affected enrollee requests a refill of the Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D plan sponsor must provide retrospective notice to the affected enrollees.**<br><br>**42 CFR § 423.120(b)(5)(i-iii); § 423.578(d)**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***<br>***Reporting Requirements for Section V: Grievances*** | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| **MR11 Desk Element** | **Formulary Education**<br><br>**The Part D plan sponsor must establish and implement policies and procedures to educate and inform enrollees concerning its formulary.**<br><br>**42 CFR § 423.120(b)(7)** | |
| **MR12 Desk Element** | **Card or Other Technology to Access Negotiated Prices**<br><br>**The Part D plan sponsor must issue and reissue, as necessary, a card or other type of technology that its enrollees may use to access negotiated prices for covered Part D drugs. The card or other technology must comply with CMS standards.**<br><br>**42 CFR § 423.120(c)**<br>**Attestation required by the PDP Solicitation: 3.5.A.13**<br>**Attestation required by the MA-PD Solicitation: N/A**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |
| **MR13 Desk Element** | **Requirements for Post-Enrollment Materials**<br><br>**The Part D plan sponsor must distribute post-enrollment materials as required by CMS, to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter. This information must be provided in writing, if requested. In addition, the Part D plan sponsor must provide written information about its grievance and appeals procedures and the process for quality of care complaints available to the enrollee through the Quality Improvement Organization (QIO) process.**<br><br>**42 CFR § 423.128(a-b); § 423.128(d)(3); § 423.505(f)(3); § 423.562(a)(2)**<br>**Attestations required by the PDP Solicitation: 3.2.2.A.3; 3.6.A.2; 3.7.A.3; 3.10.A.2**<br>**Attestations required by the MA-PD Solicitation: 3.2.2.A.3; 3.5.B.2; 3.5.A.3; 3.8.A.2**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans***<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| **MR14 Desk Element** | **Information Provided to Beneficiaries Upon Request**<br><br>**The Part D plan sponsor must provide the information required by CMS upon request of a Part D eligible individual. This information must be provided in writing, if requested.**<br><br>**42 CFR § 423.128(c); § 423.128(d)(3); § 423.505(f)(3)**<br>**Attestations required by the PDP Solicitation: 3.2.2.A.3; 3.6.A.2; 3.7.A.3; 3.10.A.2**<br>**Attestations required by the MA-PD Solicitation: 3.2.2.A.3; 3.5.B.2; 3.5.A.3; 3.8.A.2**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |
| **MR15 Desk Element** | **Toll-free Customer Call Center**<br><br>**The Part D plan sponsor must have a toll-free customer call center that is open during usual business hours and provides customer telephone service in accordance with standard business practices.**<br><br>**41 CFR § 423.128(d)(1)**<br>**Attestations required by the PDP Solicitation: 3.9.A.4; 3.10.A.3**<br>**Attestations required by the MA-PD Solicitation: 3.7.A.4; 3.8.A.3** | |
| **MR16 Desk Element** | **Internet Website**<br><br>**The Part D plan sponsor must have an Internet website that meets CMS marketing guidelines, including providing a current formulary for its Part D plan that is updated at least monthly and providing current and prospective Part D enrollees with at least 60 days notice regarding the removal or change in the preferred or tiered cost-sharing status of a drug on the formulary.**<br><br>**42 CFR § 423.128(d)(2)**<br>**Attestation required by the PDP Solicitation: 3.10.A.4**<br>**Attestation required by the MA-PD Solicitation: 3.8.A.4**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |

| Code/ Type | Chapter 3: Marketing and Beneficiary Information | Review Result |
|---|---|---|
| **MR17 Desk Element** | **Explanation of Benefits**<br><br>**The Part D plan sponsor must provide enrollees with a written explanation of benefits (EOB) in a form easily understandable to enrollees and in accordance with CMS requirements, at least on a monthly basis for those months in which the enrollees use their Part D benefits.**<br><br>**42 CFR § 128(e)**<br>**Attestations required by the PDP Solicitation: 3.9.A.3; 3.10.A.5**<br>**Attestations required by the MA-PD Solicitation: 3.7.A.3; 3.8.A.5**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |
| **MR18 Desk Element** | **Disclosure of Price Differential**<br><br>**The Part D plan sponsor must require its network pharmacies dispensing a covered Part D drug to inform enrollees of any differential between the price of that drug and the price of the lowest priced generic version of that drug that is therapeutically equivalent, bioequivalent, and available at that pharmacy, unless the particular drug being purchased is the lowest-priced therapeutically equivalent or bioequivalent version of that drug available at that pharmacy. This information must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.**<br><br>**42 CFR § 423.132(a-b)**<br>**Attestation required by the PDP Solicitation: 3.4.A.6**<br>**Attestation required by the MA-PD Solicitation: 3.4.A.6** | |

| Code/ Type | Chapter 4: Privacy and Confidentiality | Review Result |
|---|---|---|
| PR01 Desk Element | **Confidentiality and Disclosure of Health and Enrollment Information**<br><br>The Part D plan sponsor must establish procedures to safeguard beneficiary privacy and confidentiality, release information regarding medical records or other health and enrollment information only in accordance with applicable Federal and State laws or under court orders or subpoenas, maintain and ensure accuracy of enrollee health records, and ensure timely access to health records by the enrollees.<br><br>42 CFR § 423.136; § 423.505(h)(2); 45 CFR part 164 subpart C<br>Attestation required by the PDP Solicitation: 3.16.A.1<br>Attestation required by the MA-PD Solicitation: 3.15.A.1<br>PDP Solicitation: Appendices V and VI<br>MA-PD Solicitation: N/A | |
| PR02 Desk Element | **Use of SSN/HICN**<br><br>The Part D plan sponsor must use a number other than an enrollee's Social Security Number (SSN) or Healthcare Insurance Claim Number (HICN) on enrollee identification cards.<br><br>Attestation required by the PDP Solicitation: 3.15.A.1<br>Attestation required by the MA-PD Solicitation: 3.14.A.1 | |
| PR03 Desk Element | **Proper Notification and Authorization**<br><br>Prior to enrollment or at the time of enrollment, the Part D plan sponsor must notify each beneficiary of its obligations and the beneficiary's rights with respect to protected health information. The Part D plan sponsor must also obtain written authorization for all uses and disclosures not otherwise permitted under the HIPAA Privacy Rule.<br><br>42 CFR § 423.136<br>Attestations required by the PDP Solicitation: 3.15.A.2; 3.15.A.3; 3.15.A.4<br>Attestations required by the MA-PD Solicitation: 3.14.A.2; 3.14.A.3; 3.14.A.4 | |

| Code/ Type | Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| | **Drug Utilization Management** | |
| **DM01 Desk Element** | **Incentives to Reduce Costs**<br><br>**The Part D plan sponsor must have a reasonable and appropriate Drug Utilization Management (DUM) program that establishes incentives to reduce costs when medically appropriate.**<br><br>**42 CFR § 423.153(b)(1)**<br>**Attestations required by the PDP Solicitations: 3.2.2.A.2; 3.2.2.A.4**<br>**Attestations required by the MA-PD Solicitation: 3.2.2.A.2; 3.2.2.A.4**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **DM02 Desk Element** | **Preventing Over and Under Utilization**<br><br>**The Part D plan sponsor must have a reasonable and appropriate Drug Utilization Management (DUM) program that maintains policies and systems to assist in preventing over and under utilization of prescription medications.**<br><br>**42 CFR § 423.153(b)(2)**<br>**Attestation required by the PDP Solicitation: 3.2.2.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.2.2.A.1**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **DM03 Desk Element** | **Drug Utilization Management Reporting Requirements**<br><br>**The Part D plan sponsor must provide CMS with information concerning the procedures and performance of its Drug Utilization Management (DUM) program according to guidelines specified by CMS.**<br><br>**42 CFR § 423.153(b)(3)**<br>**Attestations required by the PDP Solicitation: 3.2.2.A.5; 3.13.A.15-17**<br>**Attestations required by the MA-PD Solicitation: 3.2.2.A.5; 3.11.A.12-14**<br>***Reporting Requirements for Section IV: Generic Dispensing Rate; and Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions***<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |

| Code/ Type | Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| | **Quality Assurance** | |
| **QA01 Desk Element** | **Standards for Pharmacy Practice**<br><br>**The Part D plan sponsor must require network providers to comply with minimum standards for pharmacy practice as established by the States.**<br><br>**42 CFR § 423.153(c)(1)**<br>**Attestations required by the PDP Solicitation: 3.2.3.A.1; 3.2.3.A.3**<br>**Attestations required by the MA-PD Solicitation: 3.2.3.A.1; 3.2.3.A.3** | |
| **QA02 Desk Element** | **Concurrent Drug Utilization Review**<br><br>**The Part D plan sponsor must have concurrent Drug Utilization Review (DUR) systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee at the point of sale or distribution.**<br><br>**42 CFR § 423.153(c)(2)**<br>**Attestations required by the PDP Solicitation: 3.2.3.A.1; 3.2.3.A.2; 3.2.3.A.5**<br>**Attestations required by the MA-PD Solicitation: 3.2.3.A.1; 3.2.3.A.2; 3.2.3.A.5** | |
| **QA03 Desk Element** | **Retrospective Drug Utilization Review**<br><br>**The Part D plan sponsor must have retrospective Drug Utilization Review (DUR) systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in the Part D plan, or associated with specific drugs or groups of drugs.**<br><br>**42 CFR § 423.153(c)(3)**<br>**Attestations required by the PDP Solicitation: 3.2.3.A.1; 3.2.3.A.2**<br>**Attestations required by the MA-PD Solicitation: 3.2.3.A.1; 3.2.3.A.2** | |
| **QA04 Desk Element** | **Internal Medication Error Identification and Reduction Systems**<br><br>**The Part D plan sponsor must have internal medication error identification and reduction systems that address ways to reduce medication errors and adverse drug interactions, and improve medication use.**<br><br>**42 CFR § 423.153(c)(4)**<br>**Attestations required by the PDP Solicitation: 3.2.3.A.1; 3.2.3.A.4**<br>**Attestations required by the MA-PD Solicitation: 3.2.3.A.1; 3.2.3.A.4** | |

| Code/ Type | Chapter 5: Drug Utilization Management, Quality Assurance, and Electronic Prescribing<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| **QA05 Desk Element** | **Sponsor Provision of Information**<br><br>**The Part D plan sponsor must provide CMS with information concerning the plan's quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improve medication use.**<br><br>**42 CFR § 423.153(c)(5)**<br>**Attestation required by the PDP Solicitation: 3.2.3.A.6**<br>**Attestation required by the MA-PD Solicitation: 3.2.3.A.6** | |
| | **Electronic Prescribing** | |
| **EP01 Desk Element** | **Electronic Prescribing**<br><br>**The Part D plan sponsor must establish and maintain an electronic prescription drug program that complies with CMS standards.**<br><br>**42 CFR § 423.160**<br>**Attestation required by the PDP Solicitation: 3.2.5.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.2.5.A.1** | |

| Code/ Type | Chapter 6: Pharmacy Access | Review Result |
|---|---|---|
| **PH01 Desk Element** | **Network Retail Pharmacy Access**<br><br>**The Part D plan sponsor must meet CMS standards for convenient access to Part D drugs.**<br><br>**42 CFR § 423.120(a)(1-2)**<br>**Attestation required by the PDP Solicitation: 3.4.1.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.4.1.A.1**<br>***August 1, 1005 Submission of Pharmacy Access Analyses***<br>***Meeting Retail Pharmacy Access Requirements***<br>***Note: This element is waived for MA-PDs that own and operate their own pharmacies.***<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit if they provide access through all pharmacies.***<br>***Note: This element is waived for Pacific Territories [Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands].*** | |
| **PH02 Desk Element** | **Access to Home Infusion Pharmacies**<br><br>**The Part D plan sponsor must provide adequate access to home infusion pharmacies consistent with CMS guidelines and instructions.**<br><br>**42 CFR § 423.120(a)(4)**<br>**Attestations required by the PDP Solicitation: 3.4.4.A.1-3**<br>**Attestations required by the MA-PD Solicitation: 3.4.4.A.1-3**<br>***August 1, 2005 Submission of Pharmacy Access Analyses*** | |
| **PH03 Desk Element** | **Long-Term Care Pharmacy Contracting Terms and Conditions**<br><br>**The Part D plan sponsor must offer standard contracting terms and conditions, including performance and service criteria for all long-term care (LTC) pharmacies in its Part D plan service area.**<br><br>**42 CFR § 423.120(a)(5)**<br>**Attestation required by the PDP Solicitation: 3.4.5.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.4.5.A.1**<br>**PDP Solicitation: Appendix XIII**<br>**MA-PD Solicitation: Appendix X**<br>***Long Term Care Guidance*** | |

| Code/ Type | Chapter 6: Pharmacy Access | Review Result |
|---|---|---|
| **PH04 Desk Element** | **Access to Long-Term Care Pharmacies**<br><br>**The Part D plan sponsor must contract with a sufficient number of LTC pharmacies to provide all of its plan's institutionalized enrollees convenient access to their Part D benefits.**<br><br>**42 CFR § 423.120(a)(5)**<br>**Attestation required by the PDP Solicitation: 3.4.5.A.4**<br>**Attestation required by the MA-PD Solicitation: 3.4.5.A.4**<br>***Long Term Care Guidance*** | |
| **PH05 Desk Element** | **I/T/U Pharmacy Contracting Terms and Conditions**<br><br>**The Part D plan sponsor must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies in its Part D plan service area.**<br><br>**42 CFR § 423.120(a)(6)**<br>**Attestations required by the PDP Solicitation: 3.4.6.A.1; 3.4.6.B.1**<br>**Attestations required by the MA-PD Solicitation: 3.4.6.A.1; 3.4.6.B.1**<br>**PDP Solicitation: Appendix XIII**<br>**MA-PD Solicitation: Appendix X**<br>***Information for Part D Sponsors on Contracting With Indian Health Care Providers Guidance*** | |
| **PH06 Desk Element** | **Access to I/T/U Pharmacies**<br><br>**The Part D plan sponsor must provide convenient access to Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacies.**<br><br>**42 CFR § 423.120(a)(6)**<br>**Attestations required by the PDP Solicitation: 3.4.6.A.1; 3.4.6.D**<br>**Attestations required by the MA-PD Solicitation: 3.4.6.A.1; 3.4.6.D**<br>***Information for Part D Sponsors on Contracting With Indian Health Care Providers*** | |

| Code/ Type | Chapter 6: Pharmacy Access | Review Result |
|---|---|---|
| **PH07 Desk Element** | **Any Willing Pharmacy Provision**<br><br>**The Part D plan sponsor must contract with any pharmacy that meets the plan's standard terms and conditions.**<br><br>**42 CFR § 423.120(a)(8)(i)**<br>**Attestation required by the PDP Solicitation: 3.4.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.4.A.1**<br>**PDP Solicitation: Appendix XIII**<br>**MA-PD Solicitation: Appendix X**<br>***Note: This element is waived for MA-PDs that own and operate their own pharmacies.*** | |
| **PH08 Desk Element** | **Pharmacy Network Contract Requirements**<br><br>**The Part D plan sponsor's pharmacy network contracts must meet CMS requirements.**<br><br>**42 CFR § 423.120(a)(8)(ii)**<br>**Attestations required by the PDP Solicitation: 3.4.A.2-5**<br>**Attestations required by the MA-PD Solicitation: 3.4.A.2-5**<br>**PDP Solicitation: Appendix XIII**<br>**MA-PD Solicitation: Appendix X** | |
| **PH09 Desk Element** | **Level Playing Field Between Mail Order and Retail Network Pharmacies**<br><br>**The Part D plan sponsor must permit its enrollees to receive benefits that may include a 90-day supply of covered Part D drugs at any of its retail network pharmacies instead of at a network mail-order pharmacy. Note: This element is not applicable if Part D plan does not offer mail order service.**<br><br>**42 CFR 423.120(a)(10)**<br>**Attestation required by the PDP Solicitation: 3.4.1.A.3**<br>**Attestation required by the MA-PD Solicitation: 3.4.1.A.3** | |

| Code/ Type | Chapter 6: Pharmacy Access | Review Result |
|---|---|---|
| **PH10 Desk Element** | **Out-of-Network Pharmacy Access**<br><br>**The Part D plan sponsor must provide adequate access to covered Part D drugs dispensed at out-of-network pharmacies when enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy, provided they do not access covered Part D drugs at an out-of-network pharmacy on a routine basis. The Part D plan sponsor must have reasonable rules to appropriately limit out-of-network access to Part D drugs, including CMS-required access guarantees.**<br><br>**42 CFR § 423.124(a)(1); § 423.124(c)**<br>**Attestations required by the PDP Solicitation: 3.4.2.A.1; 3.4.2.A.4**<br>**Attestations required by the MA-PD Solicitation: 3.4.2.A.1; 3.4.2.A.4** | |
| **PH11 Desk Element** | **Access in Physician Office**<br><br>**The Part D plan sponsor must provide adequate access to vaccines and other covered Part D drugs that are appropriately dispensed and administered by a physician in a physician's office.**<br><br>**42 CFR § 423.124(a)(2)**<br>**Attestation required by the PDP Solicitation: 3.4.2.A.2**<br>**Attestation required by the MA-PD Solicitation: 3.4.2.A.2** | |
| **PH12 Desk Element** | **Pharmacy Access Reporting Requirements**<br><br>**The Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public statistics indicating the availability, accessibility, and acceptability of its services.**<br><br>**42 CFR § 423.514(a)(3)**<br>**Attestation required by the PDP Solicitation: 3.13.A.19**<br>**Attestation required by the MA-PD Solicitation: 3.11.A.16**<br>***Reporting Requirements for Section V: Grievances*** | |

| Code/ Type | Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| | **Formulary** | |
| **FM01 Desk Element** | **Formulary Requirements**<br><br>**The Part D plan sponsor must use a CMS-approved Part D plan formulary.**<br><br>**42 CFR § 423.120(b)(2)** | |
| **FM02 Desk Element** | **Formulary Maintenance Requirements**<br><br>**The Part D plan sponsor must follow CMS requirements regarding changes to a Part D plan formulary.**<br><br>**42 CFR § 423.120(b)(4); § 423.120(b)(6)**<br>***Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures*** | |
| **FM03 Desk Element** | **Provision of Notice Regarding Formulary Changes**<br><br>**The Part D plan sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (SPAPs), and entities providing other prescription drug coverage prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D plan sponsor must provide retrospective notice to the parties listed above.**<br><br>**42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)**<br>***Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans*** | |

| Code/ Type | Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| | **Transition Process** | |
| **TP01 Desk Element** | **Transition Process for Enrollees**<br><br>**The Part D plan sponsor must have and implement an appropriate transition process in accordance with CMS requirements for new and existing enrollees prescribed Part D drugs not on its formulary.**<br><br>**42 CFR § 423.120(b)(3)**<br>**Attestation required by the PDP Solicitation: 3.2.3.A.7**<br>**Attestation required by the MA-PD Solicitation: 3.2.3.A.7**<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |
| **TP02 Desk Element** | **Transition Process for Residents of Long-Term Care Facilities**<br><br>**The Part D plan sponsor must have and implement an appropriate transition process for addressing the immediate needs of long-term care (LTC) residents where there is a disparity between the Part D requirements and the Medicare conditions of participation for LTC facilities. This process must cover an emergency supply or "first-fill" of non-formulary Part D drugs.**<br><br>**42 CFR § 423.120(b)(3)**<br>**Attestation required by the PDP Solicitation: 3.2.3.A.9**<br>**Attestation required by the MA-PD Solicitation: 3.2.3.A.9**<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |
| | **Pharmacy &Therapeutics Committee** | |
| **PT01 Desk Element** | **Formulary Development and Review by a Pharmacy and Therapeutics (P&T) Committee**<br><br>**The Part D plan sponsor's formulary must be developed and reviewed by a P&T Committee.**<br><br>**42 CFR § 423.120(b)(1)**<br>**Attestation required by the PDP Solicitation: 3.2.1.D.1**<br>**Attestation required by the MA-PD Solicitation: 3.2.1.D.1** | |

| Code/ Type | Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| PT02 Desk Element | **P&T Committee Membership**<br><br>The Part D plan sponsor's P&T Committee must include a majority of members who are practicing physicians and/or practicing pharmacists; include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict with the Part D plan organization and pharmaceutical manufacturers; and include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.<br><br>42 CFR § 423.120(b)(1)(i-iii)<br>Attestations required by the PDP Solicitation: 3.2.1.D.7-9<br>Attestations required by the MA-PD Solicitation: 3.2.1.D.7-9<br>PDP Solicitation: 3.2.1.C<br>MA-PD Solicitation: 3.2.1.C | |
| PT03 Desk Element | **P&T Committee Decisions**<br><br>The P&T Committee must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.<br><br>42 CFR § 423.120(b)(1)(iv)<br>Attestation required by the PDP Solicitation: 3.2.1.D.3<br>Attestation required by the MA-PD Solicitation: 3.2.1.D.3 | |
| PT04 Desk Element | **P&T Consideration of the Therapeutic Advantages of Prescription Drugs**<br><br>The P&T Committee must consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy.<br><br>42 CFR § 423.120(b)(1)(v)<br>Attestation required by the PDP Solicitation: 3.2.1.D.2<br>Attestation required by the MA-PD Solicitation: 3.2.1.D.2 | |
| PT05 Desk Element | **P&T Review of Utilization Management Processes**<br><br>The P&T Committee reviews policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.<br><br>42 CFR § 423.120(b)(1)(vi)<br>Attestation required by the PDP Solicitation: 3.2.1.D.3<br>Attestation required by the MA-PD Solicitation: 3.2.1.D.3 | |

| Code/ Type | Chapter 7: Formulary, Transition Process, and Pharmacy & Therapeutics Committee<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| **PT06 Desk Element** | **P&T Annual Evaluation of Part D plan Treatment Protocols**<br><br>**The P&T Committee evaluates, analyzes and recommends treatment protocols and procedures for the timely use of and access to both formulary and non-formulary drug products, at least annually in accordance with CMS requirements.**<br><br>**42 CFR § 423.120(b)(1)(vii)**<br>**Attestation required by the PDP Solicitation: 3.2.1.D.10**<br>**Attestation required by the MA-PD Solicitation: 3.2.1.D.10** | |
| **PT07 Desk Element** | **P&T Annual Approval of Therapeutic Classes**<br><br>**The P&T Committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.**<br><br>**Attestation required by the PDP Solicitation: 3.2.1.D.6**<br>**Attestation required by the MA-PD Solicitation: 3.2.1.D.6** | |
| **PT08 Desk Element** | **Written Documentation of P&T Committee Decisions**<br><br>**The P&T Committee must document in writing its decisions regarding formulary development and revision and utilization management activities.**<br><br>**42 CFR § 423.120(b)(1)(viii)** | |
| **PT09 Desk Element** | **P&T Review of New Chemical Entities and Clinical Indicators**<br><br>**The P&T Committee must make a reasonable effort to review within 90 days and make a decision on each new chemical entity, and new FDA clinical indicators within 180 days of its release onto the market.**<br><br>**Attestation required by the PDP Solicitation: 3.2.1.D.5**<br>**Attestation required by the MA-PD Solicitation: 3.2.1.D.5** | |

| Code/ Type | Chapter 8: Medication Therapy Management<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| **MT01 Desk Element** | **Medication Therapy Management Program Design**<br><br>**The Part D plan sponsor must have a Medication Therapy Management Program (MTMP) that is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to (i) optimize therapeutic outcomes through improved medication use, and (ii) reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries.**<br><br>**42 CFR § 423.153(d)(1)(i-ii)**<br>**Attestations required by the PDP Solicitation: 3.2.4.A.1; 3.2.4.A.4**<br>**Attestations required by the MA-PD Solicitation: 3.2.4.A.1; 3.2.4.A.4**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **MT02 Desk Element** | **Targeted Medicare Beneficiaries**<br><br>**The Part D plan sponsor must have a Medication Therapy Management Program (MTMP) that targets enrollees who (i) have multiple chronic diseases; (ii) are taking multiple Part D drugs; *and* (iii) are likely to incur annual costs for covered Part D drugs that exceed $4,000 (in year 2006).**<br><br>**42 CFR § 423.153(d)(2)**<br>**Attestation required by the PDP Solicitation: 3.2.4.A.3 and MTMP Addendum**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.3 and MTMP Addendum**<br>***Reporting Requirements for Section III: Medication Therapy Management Programs***<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **MT03 Desk Element** | **Use of Experts in Developing the Medication Therapy Management Program**<br><br>**The Part D plan sponsor must develop the Medication Therapy Management Program (MTMP) in cooperation with licensed and practicing pharmacists and physicians.**<br><br>**42 CFR § 423.153(d)(3)**<br>**Attestation required by the PDP Solicitation: 3.2.4.A.2**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.2**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |

| Code/ Type | Chapter 8: Medication Therapy Management<br>*Clinical expertise may be necessary for review* | Review Result |
|---|---|---|
| **MT04 Desk Element** | **Coordination with Care Management Plans**<br><br>**The Part D plan sponsor must coordinate the Medication Therapy Management Program (MTMP) with any care management plan established for a targeted individual under a chronic care improvement program (CCIP).**<br><br>**42 CFR § 423.153(d)(4)**<br>**Attestation required by the PDP Solicitation: 3.2.4.A.6**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.6**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **MT05 Desk Element** | **Considerations in Pharmacy Fees**<br><br>**The Part D plan sponsor must have a Medication Therapy Management Program (MTMP) fee or payment structure that takes into account the resources used and the time required by those providing MTMP services, and must disclose to CMS, upon request, the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others.**<br><br>**42 CFR § 423.153(d)(5)**<br>**Attestation required by the PDP Solicitation: 3.2.4.A.9**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.9**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **MT06 Desk Element** | **Medication Therapy Management Reporting Requirements**<br><br>**The Part D plan sponsor must provide CMS with information regarding the procedures and performance of its Medication Therapy Management Program (MTMP), according to guidelines specified by CMS.**<br><br>**42 CFR § 423.153(d)(6)**<br>**Attestations required by the PDP Solicitation: 3.2.4.A.8; 3.13.A.18**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.8; 3.11.A.15**<br>***Reporting Requirements for Section III: Medication Therapy Management Programs***<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |

| Code/ Type | Chapter 9: Coordination of Benefits/True Out of Pocket Costs | Review Result |
|---|---|---|
| **CB01 Desk Element** | **Collecting and Updating Enrollees' Other Health Insurance Information**<br><br>**The Part D plan sponsor must have a system for collecting and updating information from enrollees about their other health insurance, including whether such insurance covers outpatient prescription drugs, and must report that information to the Coordination of Benefits (COB) Contractor.**<br><br>**Attestation required by the PDP Solicitation: 3.8.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.6.A.1**<br>**PDP Solicitation: 3.8.B**<br>***Part D Coordination of Benefits Guidance*** | |
| **CB02 Desk Element** | **Coordination of Benefits with Other Prescription Drug Coverage**<br><br>**The Part D plan sponsor must have a system for exchanging payment information and coordinating payment of claims with other health insurance. The Part D plan sponsor must permit State Pharmacy Assistance Programs (SPAPs) and entities providing other prescription drug coverage to coordinate benefits with the Part D plan, including payment of premiums and coverage and payment for supplemental prescription drug benefits. The Part D plan sponsor must track the expenditures for covered Part D drugs made by other payers for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold.**<br><br>**42 CFR § 423.464(a); § 423.464(f)(2-3)**<br>**Attestations required by the PDP Solicitation: 3.8.A.2; 3.8.A.3; 3.8.A.6; 3.9.A.1**<br>**Attestations required by the MA-PD Solicitation: 3.6.A.2; 3.6.A.5; 3.7.A.1**<br>**PDP Solicitation: 3.8.C**<br>***Part D Coordination of Benefits Guidance***<br>***CMS Instructions: Requirements for Submitting Prescription Drug Event Data*** | |
| **CB03 Desk Element** | **TrOOP Status at Disenrollment**<br><br>**The Part D plan sponsor must provide the beneficiary's true out-of-pocket (TrOOP) status to the beneficiary as of the effective date of disenrollment.**<br><br>**Attestation required by the PDP Solicitation: 3.9.A.5**<br>**Attestation required by the MA-PD Solicitation: 3.7.A.5** | |

| Code/ Type | Chapter 10: Compliance Plan | Review Result |
|---|---|---|
| CP01 Desk Element | **Executive Manager and Policy-Making Body**<br><br>The Part D plan sponsor must have an executive manager and a policy-making body that exercises oversight and control over policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees. The policy-making body must control the appointment and removal of the executive manager.<br><br>42 CFR § 423.504(b)(4)(i and iii)<br>Attestations required by the PDP Solicitation: 3.1.1.A.4; 3.1.1.A.6<br>Attestation required by the MA-PD Solicitation: N/A | |
| CP02 Desk Element | **Compliance with Federal and State Standards**<br><br>The Part D plan sponsor must have and implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.<br><br>42 CFR § 423.504(b)(4)(vi)(A)<br>Attestation required by the PDP Solicitation: 3.12.A.1<br>Attestation required by the MA-PD Solicitation: 3.10.A.1 | |
| CP03 Desk Element | **Designation of Compliance Officer and Committee**<br><br>The Part D plan sponsor must have and implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management.<br><br>42 CFR § 423.504(b)(4)(vi)(B)<br>Attestation required by the PDP Solicitation: 3.12.A.2<br>Attestation required by the MA-PD Solicitation: 3.10.A.2 | |
| CP04 Desk Element | **Effective Compliance Training**<br><br>The Part D plan sponsor must have and implement a compliance plan that includes effective training and education between the compliance officer and its employees, contractors, agents, and directors.<br><br>42 CFR § 423.504(b)(4)(vi)(C)<br>Attestation required by the PDP Solicitation: 3.12.A.3<br>Attestation required by the MA-PD Solicitation: 3.10.A.3 | |

| Code/ Type | Chapter 10: Compliance Plan | Review Result |
|---|---|---|
| CP05 Desk Element | **Effective Lines of Communication**<br><br>The Part D plan sponsor must have and implement a compliance plan that includes effective lines of communication between the compliance officer and its employees, contractors, agents, directors, and members of the compliance committee.<br><br>42 CFR § 423.504(b)(4)(vi)(D)<br>Attestation required by the PDP Solicitation: 3.12.A.4<br>Attestation required by the MA-PD Solicitation: 3.10.A.4 | |
| CP06 Desk Element | **Disciplinary Guidelines and Enforcement**<br><br>The Part D plan sponsor must have and implement a compliance plan that includes the enforcement of standards through well-publicized disciplinary guidelines.<br><br>42 CFR § 423.504(b)(4)(vi)(E)<br>Attestation required by the PDP Solicitation: 3.12.A.5<br>Attestation required by the MA-PD Solicitation: 3.10.A.5 | |
| CP07 Desk Element | **Internal Monitoring and Auditing Procedures**<br><br>The Part D plan sponsor must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing.<br><br>42 CFR § 423.504(b)(4)(vi)(F)<br>Attestation required by the PDP Solicitation: 3.12.A.6<br>Attestation required by the MA-PD Solicitation: 3.10.A.6 | |
| CP08 Desk Element | **Response to Detected Offenses and Corrective Action Plan**<br><br>The Part D plan sponsor must have and implement a compliance plan that includes procedures to ensure a prompt response to detected offenses relating to the organization's contract as a Part D sponsor, and must conduct a timely, reasonable inquiry upon discovery of evidence of misconduct related to payment or delivery of prescription drug items or services under the contract. The Part D plan sponsor must also develop and conduct appropriate corrective actions in response to identified violations.<br><br>42 CFR § 423.504(b)(4)(vi)(G)<br>Attestation required by the PDP Solicitation: 3.12.A.7<br>Attestation required by the MA-PD Solicitation: 3.10.A.7 | |

| Code/ Type | Chapter 10: Compliance Plan | Review Result |
|---|---|---|
| **CP09 Desk Element** | **<u>Comprehensive Fraud and Abuse Plan</u>**<br><br>**The Part D plan sponsor must have and implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.**<br><br>**42 CFR § 423.504(b)(4)(vi)(H)**<br>**Attestation required by the PDP Solicitation: 3.12.A.8**<br>**Attestation required by the MA-PD Solicitation: 3.10.A.8**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |

| Code/ Type | Chapter 11: First-Tier and Downstream Contracts / Maintenance of Records | Review Result |
|---|---|---|
| CN01 Desk/ On-site Element | **Maintenance of Records**<br><br>The Part D plan sponsor must maintain, for 10 years, books, records, documents, and other evidence of accounting procedures and practices adhering to specified requirements. The Part D plan sponsor must maintain records for a period greater than 10 years if CMS requires based upon special need, termination, dispute, or alleged or possible fraud and abuse, based on audit findings.<br><br>42 CFR § 423.505(d); § 423.505(e)(4)<br>Attestation required by the PDP Solicitation: 3.16.A.2<br>Attestation required by the MA-PD Solicitation: 3.15.A.2 | |
| CN02 Desk Element | **Access to Facilities and Records**<br><br>The Part D plan sponsor must provide the Department of Health and Human Services (HHS), the Comptroller General, or their designee, access to its facilities and records.<br><br>42 CFR § 423.505(e) | |
| CN03 Desk Element | **Required Contract Provisions: PBM**<br><br>The Part D plan sponsor's written contracts with PBMs must comply with all CMS requirements.<br><br>42 CFR § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)<br>PDP Solicitation: 3.1.1.E; 3.1.1.F<br>MA-PD Solicitation: 3.1.1.C; 3.1.1.D | |
| CN04 Sample Element | **Required Contract Provisions: Other First Tier and Downstream Entities**<br><br>The Part D plan sponsor's written contracts with other first tier and downstream entities must comply with all CMS requirements.<br><br>42 CFR § 423.505(e)(2); § 423.505(g)(1)(i); § 423.505(i)(2-5)<br>Attestations required by the PDP Solicitation: 3.1.1.E; 3.1.1.F<br>Attestations required by the MA-PD Solicitation: 3.1.1.C; 3.1.1.D | |

| Code/ Type | Chapter 12: Claims Processing and Payment | Review Result |
|---|---|---|
| | **Claims Processing** | |
| **CL01 Desk Element** | **Online Claims Processing System**<br><br>**The Part D plan sponsor must develop and operate a real-time online claims processing system that operates according to CMS standards.**<br><br>**Attestation required by the PDP Solicitation: 3.17.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.13.A.1** | |
| **CL02 Desk Element** | **Data Elements Needed to Link Medicare Parts A, B & D Data**<br><br>**The Part D plan sponsor must submit claims data that can be linked at the individual level to Medicare Parts A & B data.**<br><br>**42 CFR § 423.329(b)(3)(i); § 422.310**<br>***Instructions: Requirements for Submitting Prescription Drug Event Data*** | |
| **CL03 Desk Element** | **Paper Claims Processing System**<br><br>**The Part D plan sponsor must develop and operate a paper claims processing system designed to pay claims submitted by non-network pharmacies on behalf of Part D plan enrollees that operates according to CMS standards.**<br><br>**Attestation required by the PDP Solicitation: 3.17.A.2**<br>**Attestation required by the MA-PD Solicitation: 3.13.A.2** | |
| **CL04 Desk Element** | **Mail Order Processing System**<br><br>**If mail order pharmacy is offered, the Part D plan sponsor's processing system must meet the three business day turnaround time from the point of receipt of prescription for in-stock items with no intervention to the point of shipment, or five business day turnaround time from the point of receipt of prescription for in-stock items with intervention to the point of shipment.**<br><br>**Attestations required by the PDP Solicitation: 3.17.A.3-4**<br>**Attestations required by the MA-PD Solicitation: 3.13.A.3-4** | |

| Code/ Type | Chapter 12: Claims Processing and Payment | Review Result |
|---|---|---|
| **CL05 Desk Element** | **Processing Systems**<br><br>**The Part D plan sponsor has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes.**<br><br>**Attestations required by PDP the Solicitation: 3.17.A.5-8**<br>**Attestations required by the MA-PD Solicitation: 3.13.A.5-8** | |
| **CL06 Desk Element** | **Disputed Claims**<br><br>**The Part D plan sponsor must have and implement policies and procedures surrounding disputed claims.**<br><br>**Attestation required by the PDP Solicitation: 3.17.A.10**<br>**Attestation required by the MA-PD Solicitation: 3.13.A.10** | |
| **CL07 Desk Element** | **Coordination With Chronic Care Improvement Programs (CCIPs)**<br><br>**The Part D plan sponsor must provide drug claims data to Chronic Care Improvement Programs (CCIPs) for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.**<br><br>**42 CFR § 423.153(d)(4)**<br>**Attestation required by the PDP Solicitation: 3.2.4.A.7**<br>**Attestation required by the MA-PD Solicitation: 3.2.4.A.7**<br>***Note: This element is waived for MA-PFFS organizations that offer a Part D Benefit.*** | |
| **CL08 Desk Element** | **Certification of Claims Data**<br><br>**The Part D plan sponsor's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, or first-tier or downstream entity, must certify each submission of claims data are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.**<br><br>**42 CFR § 423.505(k)(3)** | |

| Code/ Type | Chapter 12: Claims Processing and Payment | Review Result |
|---|---|---|
| | **Payment** | |
| **PA01 Desk Element** | **Certification of Monthly Enrollment and Payment Data Relating to CMS Payment**<br><br>**Payments to a Part D plan sponsor are conditioned upon its submittal and certification of enrollment, disenrollment, and change transactions to CMS each month. The Part D plan sponsor must submit reconciled enrollment/payment reports and signed attestation forms to CMS within 45 days of data availability.**<br><br>**42 CFR § 423.505(k)(2)**<br>**Attestations required by the PDP Solicitation: 3.14.A.6-8**<br>**Attestations required by the MA-PD Solicitation: 3.12.A.2-3**<br>**PDP Solicitation: Appendix IX**<br>**MA-PD Solicitation: Appendix VII** | |
| **PA02 Desk Element** | **Submission of Cost Data**<br><br>**Within 6 months of the end of a coverage year, the Part D plan sponsor must provide cost data concerning direct subsidies, reinsurance, low income cost-sharing subsidies, and risk corridors to CMS.**<br><br>**42 CFR § 423.336(c)(1); § 423.343(c)(1); § 423.343(d)(1)** | |
| **PA03 Desk Element** | **Overpayment and Underpayment Requirements**<br><br>**The Part D plan sponsor must develop and have available to CMS upon request, policies and procedures that include a description of how overpayments and underpayments are handled, as well as recovery procedures. The Part D plan sponsor must also report to CMS data related to overpayments associated with Part D benefits.**<br><br>**Attestation required by the PDP Solicitation: 3.17.A.9**<br>**Attestation required by the MA-PD Solicitation: 3.13.A.9**<br>***Reporting Requirements for Section IX: Overpayments*** | |

| Code/ Type | Chapter 13: Grievances, Coverage Determinations, and Appeals | Review Result |
|---|---|---|
| | **Grievances** | |
| **GV01 Sample Element** | **Complaint Categorization (Grievances vs. Coverage Determinations)**<br><br>**The Part D plan sponsor must promptly and correctly determine and inform the enrollee whether a complaint is subject to its grievance procedures or its coverage determination procedures.**<br><br>**42 CFR § 423.564(b)** | |
| **GV02 Desk Element** | **Grievance Policies and Procedures**<br><br>**The Part D plan sponsor must establish and maintain policies and procedures for tracking and addressing the timely hearing and resolution of all oral and written enrollee grievances including but not limited to the following: fraud and abuse, enrollment/disenrollment, benefit package, pharmacy access/network, marketing, customer service, confidentiality/privacy, and quality of care. The Part D plan sponsor must also maintain records of such grievances.**<br><br>**42 CFR § 423.562(a)(1)(i); § 423.564(a-b); § 423.564(g)**<br>**Attestations required by the PDP Solicitation: 3.6.A.1; 3.6.A.3-4**<br>**Attestations required by the MA-PD Solicitation: 3.5.B.1; 3.5.B.3-4**<br>***Reporting Requirements for Section V: Grievances*** | |
| **GV03 Desk Element** | **Access to Grievance Records**<br><br>**The Part D plan sponsor must provide to CMS upon request access to records on all grievances received both orally, and in writing.**<br><br>**Attestation required by the PDP Solicitation: 3.6.A.4**<br>**Attestation required by the MA-PD Solicitation: 3.5.B.4** | |
| **GV04 Desk Element** | **Grievance Process Training**<br><br>**The Part D plan sponsor will train relevant staff and subcontractors on its grievance policies and procedures.**<br><br>**Attestation required by the PDP Solicitation: 3.6.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.5.B.1** | |
| **GV05 Sample Element** | **Timely Notification of Grievance Disposition**<br><br>**The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the Part D plan sponsor receives the oral or written grievance (or an additional 14 days if an extension is requested by the enrollee or justified by the Part D plan sponsor). If the Part D plan** | |

| Code/ Type | Chapter 13: Grievances, Coverage Determinations, and Appeals | Review Result |
|---|---|---|
| | **sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.**<br><br>**42 CFR § 423.564(e)(1-2)**<br>**Attestation required by the PDP Solicitation: 3.6.A.1**<br>**Attestation required by the MA-PD Solicitation: 3.5.B.1** | |
| **GV06 Sample Element** | **Method of Grievance Response**<br><br>**The Part D plan sponsor must respond to all written grievances in writing (including facsimile). If the enrollee orally submits a grievance and requests a written response, the Part D plan sponsor must respond in writing.**<br><br>**42 CFR § 423.564(e)(3)(i-ii)** | |
| **GV07 Desk Element** | **Grievance Response – Quality of Care**<br><br>**The Part D plan sponsor must respond in writing to all grievances related to the quality of care. The response must include a description of the enrollee's right to file a written complaint with the Quality Improvement Organization (QIO). If a complaint is submitted to the QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.**<br><br>**42 CFR § 423.564(e)(3)(iii)** | |
| **GV08 Desk Element** | **Timely Response to Expedited Grievances**<br><br>**The Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination or an expedited redetermination, and the enrollee has not yet purchased or received the drug that is in dispute.**<br><br>**42 CFR § 423.564(f)** | |
| | **Coverage Determinations** | |
| **CD01 Desk Element** | **Notices in Network Pharmacies**<br><br>**The Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.**<br><br>**42 CFR § 423.562(a)(3)** | |
| **CD02 Desk Element** | **Coverage Determination Policies and Procedures**<br><br>**The Part D plan sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for coverage determinations (expedited and standard) regarding basic coverage and** | |

| Code/ Type | Chapter 13: Grievances, Coverage Determinations, and Appeals | Review Result |
|---|---|---|
| | **supplemental benefits, and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. These procedures must address unplanned transitions, and actions that are coverage determinations as defined in § 423.566(b).**<br><br>**The Part D plan sponsor must establish and maintain efficient and convenient means for individuals (including enrollees, their appointed representatives, or their prescribing physicians) to submit oral or written requests for coverage determinations, document all oral requests in writing, and maintain the documentation in a case file.**<br><br>**The Part D plan sponsor must establish and maintain policies and procedures for tracking and addressing the timely review and resolution of all enrollee requests for re-determinations, reconsiderations by the Independent Review Entity (IRE), and reviews by the Administrative Law Judge (ALJ) received both orally and in writing.**<br><br>**42 CFR § 423.566(a); § 423.566(b); § 423.566(c); § 423.570(c)(1-2)**<br>**Attestations required by the PDP Solicitation: 3.7.A.1; 3.7.A.4**<br>**Attestations required by the MA-PD Solicitation: 3.5.A.1; 3.5.A.4**<br>***Reporting Requirements Section VII: Appeals***<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |
| **CD03 Desk Element** | **Access to Exceptions and Appeals Records**<br><br>**The Part D plan sponsor must provide to CMS, upon request, access to all exceptions and appeals records.**<br><br>**Attestation required by the PDP Solicitation: 3.7.A.5**<br>**Attestation required by the MA-PD Solicitation: 3.5.A.5** | |
| **CD04 Sample Element** | **Timely Notification of Coverage Determination Concerning Drug Benefit**<br><br>**In response to a drug benefit request, the Part D plan sponsor must notify the enrollee (and the prescribing physician involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement. If the coverage determination was denied and the initial notification was provided orally, the Part D plan sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. Failure to notify the enrollee within the timeframe constitutes an adverse coverage determination requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.**<br><br>**42 CFR § 423.568(a); § 423.568(e); § 423.578(c)(2)**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |
| **CD05 Sample** | **Timely Notification of Coverage Determination Concerning Payment** | |

| Code/ Type | Chapter 13: Grievances, Coverage Determinations, and Appeals | Review Result |
|---|---|---|
| Element | The Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the payment request. If the coverage determination was denied and the initial notification was provided orally, the Part D plan sponsor must send the written notice to the enrollee within 3 calendar days of the oral notice. Failure to notify the enrollee within the timeframe constitutes an adverse determination requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.<br><br>42 CFR § 423.568(b); § 423.568(e)<br>*Note: Further guidance on requirements for this element will be forthcoming from CMS.* | |
| CD06 Sample Element | Denial Notice Requirements for Coverage Determinations<br><br>If the Part D plan sponsor makes an adverse determination, in whole or in part, it must provide the enrollee with written notification, using approved notice language that is readable and understandable, states the specific reasons for the denial, and informs the enrollee of his or her right to a redetermination.<br><br>42 CFR § 423.568(c-d) | |
| CD07 Sample Element | Decision to Accept or Deny Request for Expedited Coverage Determination<br><br>The Part D plan sponsor must promptly and correctly determine whether a complaint is a standard coverage determination or an expedited coverage determination. The Part D plan sponsor must have a means for issuing prompt decisions on expediting a coverage determination if it determines, based on the enrollee's request, or as indicated in the prescribing physician's request, that applying the standard timeframe for making a coverage determination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.<br><br>42 CFR § 423.570(c)(3) | |
| CD08 Sample Element | Timely Notification Following Decision to Deny Request for Expedited Coverage Determination<br><br>If the Part D plan sponsor decides not to expedite a coverage determination, it must automatically transfer the request to the standard timeframe, provide prompt oral notice to the enrollee and prescribing physician of the decision not to expedite, and provide equivalent written notice within 3 calendar days of the oral notice.<br><br>42 CFR § 423.570(d); § 423.572(a) | |
| CD09 Sample Element | Notice Content Requirements for Decision to Deny Request for Expedited Coverage Determination<br><br>The notice for the decision to deny a request for an expedited coverage determination must provide an explanation that the Part D plan sponsor must process the request using the 72 hour timeframe for standard determinations; inform the enrollee of the right to file an expedited grievance; inform the enrollee of the right to resubmit a request for an expedited determination with | |

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| | **the prescribing physician's support; and provide instructions about the Part D plan's grievance process and its timeframes.**<br><br>**42 CFR § 423.570(d)(2)** | |
| **CD10 Desk Element** | **Timely Notification of Expedited Coverage Determination**<br><br>**The Part D plan sponsor must make its expedited coverage determination and notify the enrollee of its decision (adverse or favorable), as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement. If the decision is adverse and the Part D plan sponsor first notifies the enrollee of the determination orally, the Part D plan sponsor must mail written confirmation to the enrollee within 3 calendar days of the oral notification. Failure to notify the enrollee within the timeframe constitutes an adverse determination requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.**<br><br>**42 CFR § 423.570(e); § 423.572(a-b); § 423.572(d); § 423.578(c)(2)**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |
| **CD11 Desk Element** | **Notice Content Requirements for Expedited Coverage Determination**<br><br>**The notice of any expedited coverage determination must state the specific reasons for the determination in understandable language. If the determination is not completely favorable, the notice must also: (1) include information concerning the enrollee's right to a redetermination; (2) describe both the standard and expedited redetermination processes, including the enrollee's right to request, and conditions for obtaining, an expedited redetermination, and the rest of the appeals process; and (3) comply with any other requirements specified by CMS.**<br><br>**42 CFR § 423.572(c)** | |
| | **Exceptions** | |
| **CE01 Desk Element** | **Exceptions Procedures and Criteria (Tiered Cost-Sharing)**<br><br>**The Part D plan sponsor must establish and maintain reasonable and complete exceptions procedures, *subject to CMS' approval*, for exceptions requests to the Part D plan sponsor's tiered cost-sharing structure. The exceptions procedures must address situations where a formulary's tiering structure changes during the year, and an enrollee is using a drug affected by the change. The Part D plan sponsor must grant an exception for non-preferred drugs when medically necessary and consistent with the prescribing physician's statement that meets CMS criteria. The Part D plan sponsor's tiered cost-sharing exceptions process and exception criteria must meet CMS requirements including for unplanned transitions.**<br><br>**42 CFR § 423.578(a)(1-2); § 423.578(a)(4)**<br>**Attestation required by the PDP Solicitation: 3.7.A.2 and EP Attestation Addendum** | |

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| | **Attestation required by the MA-PD Solicitation: 3.5.A.2 and EP Attestation Addendum**<br>***Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions***<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |
| **CE02 Desk Element** | **Exceptions Procedures and Criteria (Non-Formulary Drugs)**<br><br>**The Part D plan sponsor must establish and maintain exceptions procedures, *subject to CMS' approval*, for receipt of an off-formulary drug. The Part D plan sponsor must grant an exception for a non-formulary Part D drug whenever it determines that the drug is medically necessary, consistent with the prescribing physicians' statement that meets CMS criteria, and that the drug would be covered but for the fact that it is an off-formulary drug. The Part D plan sponsor's formulary exceptions process and exception criteria must meet CMS requirements including for unplanned transitions.**<br><br>**42 CFR § 423.578(b); § 423.578(b)(1); § 423.578(b)(2); § 423.578(b)(5)**<br>**Attestation required by the PDP Solicitation: 3.7.A.2 and EP Attestation Addendum**<br>**Attestation required by the MA-PD Solicitation: 3.5.A.2 and EP Attestation Addendum**<br>***Reporting Requirements for Section VI: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions***<br>***Information for Part D Sponsors on Requirements for a Transition Process*** | |
| **CE03 Desk Element** | **Approval of Tiering and Non-Formulary Exceptions Requests**<br><br>**Following approval of a request for a tiering or a non-formulary exception, the Part D plan sponsor must apply the same cost-sharing level as preferred drugs, and cannot require an approval for a refill or a new prescription following the initial prescription, provided that (i) the enrollee's prescribing physician continues to prescribe the drug; (ii) the drug continues to be considered safe for treating the enrollee's disease or medical condition; and (iii) the enrollment period has not expired. For non-formulary exceptions, the Part D plan sponsor must place the approved non-formulary drug in an existing cost-sharing tier.**<br><br>**42 CFR § 578(c)(3); § 423.578(c)(4)(i-ii)**<br>**EP Attestation Addendum** | |
| | **Redeterminations** | |
| **RE01 Desk Element** | **Request for Redeterminations (Standard)**<br><br>**The Part D plan sponsor must have policies, procedures, and systems in place that allow it to accept written requests for standard redeterminations of coverage determinations filed within 60 calendar days of the notice of the coverage determination. The Part D plan sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to hand-deliver or present in writing, evidence and allegations of fact or law related to the issue in dispute.**<br><br>**42 CFR § 423.582(a-b); § 423.586**<br>**Attestation required by the PDP Solicitation: 3.7.A.4**<br>**Attestation required by the MA-PD Solicitation: 3.5.A.4** | |

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| RE02 Desk Element | **Request for Redeterminations (Expedited)**<br><br>**The Part D plan sponsor must establish and maintain an efficient and convenient means for an enrollee or a prescribing physician acting on behalf of an enrollee to submit oral or written requests for expedited redeterminations, document all oral requests in writing, and maintain the documentation in a case file. The Part D plan sponsor must provide the enrollee or the prescribing physician with a reasonable opportunity to present in person or in writing evidence and allegations of fact or law related to the issue in dispute. Since the opportunity to submit evidence is limited, the Part D plan sponsor must inform the enrollee or the prescribing physician of the conditions for submitting such evidence.**<br><br>**42 CFR § 423.584(c)(1); § 423.586**<br>**Attestation required by the PDP Solicitation: 3.7.A.4**<br>**Attestation required by the MA-PD Solicitation: 3.5.A.4** | |
| RE03 Sample Element | **Decision to Accept or Deny Request for Expedited Redetermination**<br><br>**The Part D plan sponsor must promptly decide whether to expedite the redetermination if it determines, based on the enrollee's request, or as indicated in the prescribing physician's request, that applying the standard timeframe for making a redetermination may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.**<br><br>**42 CFR § 423.584(c)(2)** | |
| RE04 Sample Element | **Actions Following Decision to Deny Request for Expedited Redetermination**<br><br>**If the Part D plan sponsor denies a request for an expedited redetermination, it must automatically transfer the request to the standard redetermination timeframe, provide prompt oral notice to the enrollee, according to CMS requirements, and provide equivalent written notice within 3 calendar days of the oral notice.**<br><br>**42 CFR § 423.584(d-e)** | |
| RE05 Sample Element | **Timely Notification and Effectuation of Standard Redetermination Concerning Covered Drug Benefit**<br><br>**If the Part D plan sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its original adverse coverage determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it received the request for a standard redetermination, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D plan sponsor must effectuate it as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.** | |

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| | **42 CFR § 423.590(a)(1-2); § 423.590(c); § 423.590(g)(1-4); § 423.636(a)(1)**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |
| **RE06 Sample Element** | **<u>Timely Notification and Effectuation of Standard Redetermination Concerning Payment</u>**<br><br>**If the Part D plan sponsor makes a redetermination that is favorable for the enrollee, or affirms in whole or in part its adverse coverage determination, it must issue its redetermination (in writing for the adverse redeterminations) no later than 7 calendar days from the date it received the request, meeting CMS requirements. For favorable redeterminations for the enrollee, the Part D plan sponsor must authorize the payment within 7 calendar days from the date it receives the request for redetermination. It must then make the payment no later than 30 calendar days after the date it receives the request for redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.**<br><br>**42 CFR § 423.590(b-c); § 423.590(g)(1-4); § 423.636(a)(2)**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |
| **RE07 Sample Element** | **<u>Timely Notification of Expedited Redetermination and Request for Medical Information</u>**<br><br>**If a Part D plan sponsor grants a request for expedited redetermination, it must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. If medical information is necessary, the Part D plan sponsor must make the request within 24 hours of receiving the initial request for an expedited redetermination. Failure to notify the enrollee within the timeframe constitutes an adverse redetermination decision requiring the Part D plan sponsor to forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication timeframe. The Part D plan sponsor must also inform the enrollee when case is forwarded to IRE.**<br><br>**42 CFR § 423.584(e); § 423.590(d-e); 423.638(a)**<br>***Note: Further guidance on requirements for this element will be forthcoming from CMS.*** | |
| **RE08 Sample Element** | **<u>Expedited Coverage Redetermination Reversals</u>**<br><br>**If, on an expedited redetermination of a request for benefit, the Part D plan sponsor reverses, in whole or in part, its coverage determination, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.**<br><br>**42 CFR § 423.638(a)** | |
| **RE09 Desk Element** | **<u>Review of Adverse Coverage Determinations</u>**<br><br>**The Part D plan sponsor must ensure that a person or persons who were not involved in making the coverage determination** | |

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| | **conducts the redetermination. When the issue is a denial based on lack of medical necessity, the Part D plan sponsor must ensure the redetermination is made by a physician with the expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician.**<br><br>**42 CFR § 423.590(f)(1-2)** | |
| **RE10 Sample Element** | **Timely Transfer to IRE Upon Reconsideration Request**<br><br>**In cases where an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file, the Part D plan sponsor must transfer the case file to the IRE within timeframes specified by CMS.**<br><br>***Note: Guidance on requirements for this element will be forthcoming from CMS.*** | |
| | **Reversals by other than Part D Plan Sponsors** | |
| **RV01 Sample Element** | **Effectuation of Third Party Reversals – Benefits (Standard)**<br><br>**If, on appeal of a request for benefit, the Part D plan sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires but no later than 72 hours after the date it receives notice reversing the determination. The Part D plan sponsor must also inform the IRE that the organization has effectuated the decision.**<br><br>**42 CFR § 423.636(b)(1)** | |
| **RV02 Sample Element** | **Effectuation of Third Party Reversals – Payment (Standard)**<br><br>**If, on appeal of a request for payment, the Part D plan sponsor 's determination is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D plan sponsor must authorize the payment within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must also inform the IRE that the organization has effectuated the decision.**<br><br>**42 CFR § 423.636(b)(2)** | |
| **RV03 Sample Element** | **Effectuation of Third Party Reversals – Benefits (Expedited)**<br><br>**If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the Independent Review Entity (IRE), or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health requires but no later than 24 hours after the date it receives notice reversing the determination. The Part D plan sponsor must also inform the IRE that the organization has effectuated the decision.** | |

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| | **42 CFR § 423.638(b)** | |

| Code/ Type | Chapter 14: Licensure and Solvency<br>For MA-PD sponsors, CMS granted a waiver of the requirement that Part D plan sponsors must be licensed to bear risk in the state in which they intend to operate. This requirement is duplicative of Medicare Advantage Organization requirements for licensure and solvency under 42 CFR §422.6(i), 42 CFR §422.400, and 42 CFR §422.501. (42 CFR §423, subpart I, excepting § 423.440) | Review Result |
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| **LS01 Desk Element** | **State Licensure or Waiver Status**<br><br>**The Part D plan sponsor must have a risk bearing state license or an active CMS-approved waiver in place.**<br><br>**42 CFR § 423.401(a)(1); § 423.410(e)(1); § 423.410(e)(3); § 423.504(b)(2)**<br>**Attestation required by the PDP Solicitation: 3.1.3.A.1**<br>**PDP Solicitation: Appendix IV**<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **LS02 Desk Element** | **Temporary State License Waiver for Regional Plans**<br><br>**A Part D plan sponsor operating in more than one State in a region, and licensed in at least one State in the region, must have a current CMS-approved temporary regional plan waiver for the State(s) in which it is not licensed.**<br><br>**42 CFR § 423.415**<br>**Attestations required by the PDP Solicitation: 3.1.3.A.3; 3.1.3.A.4**<br>**PDP Solicitation: Appendix IV**<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **LS03 Desk Element** | **Financial Solvency and Capital Adequacy Standards**<br><br>**A Part D plan sponsor that is not licensed by a state and for which a waiver application is approved by CMS (single state licensure waiver) must maintain reasonable financial solvency and capital adequacy in accordance with CMS standards.**<br><br>**42 CFR § 423.420(b)**<br>**Attestation required by the PDP Solicitation: 3.1.3.A.7**<br>**PDP Solicitation: 3.1.3.B; Appendix X**<br>***Note: Refer to MA Guide for applicable MA-PD element.*** | |
| **LS04 Desk Element** | **Financial Reporting Requirements**<br><br>**The Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, enrollees, and the general public, information demonstrating that it has a fiscally sound operation.**<br><br>**42 CFR § 423.505(f)(1)(i); § 423.514(a)(4); § 423.514(f)**<br>**Attestation required by the PDP Solicitation: 3.13.A.3**<br>***Reporting Requirements for Section XI: Licensure and Solvency, Business Transactions and Financial Requirements*** | |